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POLICY ISSUE

(NEGATIVE CONSENT)

December 10, 1996

SECY-96-249

FOR: The Commissioners

FROM: James M. Taylor
Executive Director for Operations

SUBJECT: STAFF RESPONSE TO SRM ON SECY-96-147 REGARDING REDUCING NEED
FOR EXEMPTIONS AND CONSISTENCY OF THE EXEMPTION PROCESS

PURPOSE:

To provide the Commission with a follow up paper as requested in the revised staff requirements memorandum dated September 12, 1996, regarding SECY-96-147, "Planning for Pursuing Regulatory Improvement in the Area of Exemptions Granted to Regulations."

SUMMARY:

In SECY-96-147 (dated July 1, 1996), the staff described the basis and the process the staff uses relative to "recurring exemptions" and proposed to implement a mechanism to improve the process so as to reduce the need for future exemptions. As described in Secy-96-147, the staff has implemented the processes described to reduce the need for future exemptions, and they are and will continue to be incorporated into the Rulemaking Activity Plan that is submitted to the Commission for approval on a semi-annual basis. In the September 12, 1996 SRM, the Commission informed the staff that it did not object to the staff's proposals but asked that specific issues be addressed in a follow-up Commission paper. This paper responds to the Commission's request and presents the results of the staff's review of the adequacy and completeness of justifying elements for granting exemptions as stated in 10 CFR 50.12, an evaluation of the need for additional exemption evaluation elements elsewhere in the regulations and corresponding rulemaking, and an evaluation of the internal process for the evaluation of exemption requests.

CONTACT:
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(301) 415-6202

NOTE: TO BE MADE PUBLICLY AVAILABLE WHEN THE
FINAL SRM IS MADE AVAILABLE

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BACKGROUND:

In order to respond to the Commission's request, the staff conducted a review of exemptions granted to reactor and non-reactor licensees, an evaluation of the process for granting exemptions as implemented by NRR and NMSS, and a review of the need for regulations applicable to NMSS applicants and licensees to include specific attributes or elements relative to exemptions.

DISCUSSION:Adequacy of the Justifying Elements in 10 CFR 50.12:

A sample of exemptions issued by NRR during the past 10 years was examined for specific problems and issues related to the adequacy of §50.12. Within the last year the number of exemptions considered was approximately ten per quarter and it is expected to decline. The project managers that had prepared the most recent of these exemptions were interviewed to assess the adequacy of §50.12 and to probe for any proposals for improvements to §50.12 or to the overall exemption approval process. Separately, NRR Project Directors and licensing assistants were interviewed in a similar manner to gain their perspectives from an oversight responsibility point of view. Finally, OGC management was interviewed for insights on the adequacy of both the NRR staff's ability to document the findings appropriate to the justifying elements and the adequacy of the elements to cover all appropriate circumstances.

The results of this evaluation revealed that the elements specified in §50.12 are both adequately encompassing and appropriate for making determinations regarding the acceptability of granting exemptions. No cases were found in the sample evaluated for which the criteria did not apply or were inappropriate. Therefore, the NRR staff recommends no changes to the special circumstance provisions currently contained in §50.12.

The Need for Exemption Evaluation Elements Elsewhere in the Regulations:

All CFR Parts applicable to NMSS licensees contain or reference a generic exemption clause entitled, "Specific Exemptions," which normally states: "The Commission may, upon application by any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest." This general criterion of "...authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest..." is used by the NMSS staff in considering licensee or certificate holder requests for exemptions in concert with the specific policies and procedures established by NMSS. In addition, the provisions of 50.12 are considered in reviewing certificate holder requests for exemptions.

To determine whether those parts of the regulations dealing with material licensees and certificate holders need to include specific attributes or elements similar to 50.12, the NMSS staff reviewed office policies, guidance provided to licensees, and the criteria codified in 10 CFR 50.12 for

applicability to all the types of materials licensees. In addition, a recent review of exemption requests identified that approximately 200 were granted over at least a 5 year period or longer. A review of these revealed no cases where an exemption was inappropriately granted or where there was a significant need for additional criteria. The staff found that the general criterion above, along with the internal policies and procedures, was adequate for considering exemption requests for the range of licensed activities and variety of circumstances that NMSS faces.

Specifically, the NMSS staff found that the infrastructure, policies, and procedures in existence for over 10-years have ensured consistent review of exemption requests and allowed for identification of necessary rule changes. Also, recent assessments and improvements in procedures and guidance regarding evaluation of licensee exemption requests have been made. Further, there is a wide diversity of materials licensee requirements, unique applications, and manifold applications and operational characteristics which must be addressed by the regulations. These observations, combined with the agency trend toward performance rather than prescriptive requirements, as well as the national trend to reduce regulatory burden and regulations in general, have led the NMSS staff to conclude that rulemaking to codify criteria similar to §50.12 provisions applicable to materials licensees and certificate holders would not substantially improve the current process.

The Internal Process and Staff Training for Evaluation of Exemption Requests:

NRR Licensees:

The process for review and issuance of exemptions to regulations applicable to Part 50 licenses is similar to the process used for license amendment requests that is described in NRR Office Letter 803, "Technical Specifications Review Procedures." However, there are differences between the two processes, such as: signature authority, the need to prepare an environmental assessment for an exemption (not required for most license amendments), and public noticing requirements. At present, there is no training for the NRR staff specifically dealing with the process or review criteria for exemptions. Staff training occurs on-the-job, working with project managers, project directors, and licensing assistants who have had considerable experience in issuing exemptions over the years. However, the working version of the NRC Project Manager's Handbook, available on the NRC-LAN, includes a general description of the exemption process, requirements for issuance of environmental assessments, and information on the recently made process changes that require exemptions to be coordinated with the Office of the Chairman prior to their approval by the Director, NRR. Following the next revision to the office guidance documents, NRR plans to follow-up with refresher training on the revisions for project management staff.

Quality and consistency of exemption packages and the appropriate application of the justifying elements of 50.12 are verified during concurrence review. A typical exemption request is concurred in by the NRR licensing assistant, the responsible project manager, the NRR technical review management staff, the NRR Project Director, the Reactor Projects Division Director, the Associate Director for Projects, the Director of NRR, and OGC. Since exemption packages

are funneled through the same unit in OGC, the NRR staff has found OGC's review and concurrence to be an extremely valuable check on the adequacy and consistency of exemption packages. As part of the review of an exemption request, NRR researches prior precedents, that is, previously issued exemptions on the same topic or related topics, to evaluate whether the technical information provided by the licensee in its application is sufficient and whether a similar staff finding is appropriate. The practices of using prior precedents and relying on the concurrence process have worked well to ensure the quality and consistency of exemption packages.

NMSS Licensees:

NMSS established a Policy and Guidance Directive (P&GD) in 1984 to ensure consistency in review and approval of licensee exemption requests. The P&GD contains guidance on evaluating exemption requests from licensees. The general information needed by the NRC staff, as outlined in the P&GD, directs the staff to document: a description of the licensee's or certificate holder's request for exemption, circumstances surrounding the specific exemption request and justification as to why it is needed, alternatives that have been considered, and a description of how the request provides an equivalent level of safety which may include a description of compensatory measures the licensee or certificate holder would implement. Following the NMSS technical review either recommending approval or denial, OGC reviews the request and the staff's response. The staff plans to develop an office policy and procedures letter to describe the common criteria and procedures to be used within each office division responsible for review of exemption requests.

Staff training in handling exemption requests includes qualification as a license reviewer in accordance with Manual Chapter 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." In addition, the manual requires reviews of appropriate policy and guidance directives such as those specific to granting of exemption requests.

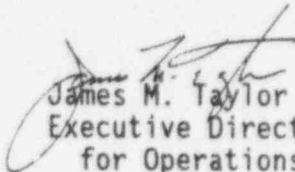
Based upon their reviews, both NRR and NMSS are satisfied with their current processes and procedures. The processes and procedures used ensure that the evaluations are conducted consistently and the elements used for evaluation are adequate. However, both offices are making improvements to their processes for handling exemptions but do not anticipate significant changes at this time.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper.

RECOMMENDATION:

Unless otherwise directed by the Commission, the staff intends to proceed as described above within 10 days of the date of this paper.


James M. Taylor
Executive Director
for Operations

Enclosures:

1. Memorandum from Thomas T. Martin, NRR,
to Bill M. Morris, RES, dated November 21, 1996.
2. Memorandum from Carl J. Paperiello, NMSS,
to David L. Morrison, RES, dated November 18, 1996.

SECY NOTE: In the absence of instructions to the contrary, SECY will notify the staff on Friday, December 27, 1996 that the Commission, by negative consent, assents to the action proposed in this paper.

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

November 21, 1996

MEMORANDUM TO: Bill M. Morris, Director
Division of Regulatory Applications
Office of Nuclear Regulatory Research

FROM: Thomas T. Martin, Director
Division of Reactor Program Management
Office of Nuclear Reactor Regulation *Thomas T. Martin*

SUBJECT: INFORMATION FOR FOLLOW-UP COMMISSION PAPER ON EXEMPTIONS
(WITS 9600046)

Attached is the Office of Nuclear Reactor Regulation's (NRR's) input for the Commission paper you are preparing in response to the Staff Requirements Memorandum on SECY-96-147 (Planning for Pursuing Regulatory Improvement in the Area of Exemptions Granted to Regulations) dated August 1, 1996. Please direct all inquiries on this effort to Ms. Melinda Malloy (email: MXM; phone: 415-1178) of the Generic Issues and Environmental Projects Branch (PGEB) of my division.

Attachment: Exemptions for Part 50 Licensees

EXEMPTIONS FOR PART 50 LICENSEES

Experience

In 1985, the Commission revised 10 CFR 50.12 to state more clearly the circumstances for which the Commission believes that exemptions to Part 50 are warranted (special circumstances).^{*} Since then, NRC has issued more than 1000 exemptions using the 50.12 special circumstances provisions.

For the past five fiscal years (FYs) (FY 92 through FY 96), NRR has approved an average of about 100 exemptions per fiscal year, or about one exemption per plant per year. For the prior five fiscal years (FY 87 through FY 91), NRR issued about 130 exemptions per fiscal year. In this 10-year period, nearly half of all exemptions sought pertained to Appendix J (containment leak testing) or Appendix R (fire prevention and protection) to 10 CFR Part 50. Over the past 9 months, there has been a marked decline in the number of exemptions issued; the number of exemptions issued has dropped to approximately ten per quarter. This decline is believed to be the result of a combination of factors. These factors include NRC's emphasis on compliance with the regulations or their improvement, in lieu of dealing with regulatory issues through vehicles such as exemptions, increased agency sensitivity and scrutiny of requests, fewer licensee submittals, and some denials. Based on this information, the staff expects that the number of exemptions (to any part of 10 CFR) will continue to decline.

Internal Procedures and Training on Review and Issuance of Exemptions

Overall, the number of exemptions processed for a specific plant per year is a relatively small percentage of the total number of licensing actions processed for that plant. The process for review and issuance of exemptions to regulations applicable to Part 50 licenses is not significantly different from the process used for license amendment requests. NRR Office Letter 803, "Technical Specifications Review Procedures," describes the basic framework for processing license amendment requests, but does not discuss how the framework is adjusted for the processing of exemptions. The differences in signature authority between exemptions and license amendments are delineated in another office procedure^{**}. Other differences, such as the requirement to pre-notice license amendments for a public hearing opportunity but not exemptions, are learned by NRR's project management staff primarily through on-the-job training, working with project managers, project directors, and licensing assistants who have had considerable experience in issuing exemptions over the years. The LAN-based working version of the NRC Project Manager's Handbook includes a general description of the exemption process and information on the recently established process changes that require exemptions to be coordinated with the Office of the Chairman prior to their approval by the Director, NRR. The PM Handbook also addresses the requirement to issue an environmental assessment for exemptions (not required for most license amendments). At present, there is no formal training for NRR staff specifically dealing with the process or review criteria for exemptions.

^{*}50 FR 50777, December 12, 1985.

^{**}NRR Office Letter 101, "Delegation of Signature Authority."

To ensure that the exemption review process is documented more fully, NRR intends to make appropriate revisions to office guidance documents and follow-up with refresher training on the revisions for project management staff. These actions have been added to and will be tracked under the NRR Associate Director for Projects Process Improvement Plan (Item 59). A description of the process for reviewing exemptions is provided in the attachment.

Consistency of Exemption Review Process in NRR

The review of prior precedents and the concurrence process have been effective in ensuring that requests for exemption from specific requirements of 10 CFR Part 50 are reviewed, the justifying elements of 50.12 are applied in a consistent manner, and staff efficiency is maximized. The project manager is responsible for ensuring that the staff performs an evaluation of the circumstances requiring the exemption and for ensuring that at least one of the unique circumstances given in 50.12 has been met. In doing so, project managers often use previously issued exemptions on the same topic or related topics to evaluate whether the technical information provided by the licensee is sufficient and whether a similar staff finding is appropriate.

Quality and consistency of exemption packages and the appropriate application of the justifying elements of 50.12 are also verified during concurrence review. A typical exemption request is concurred in by the NRR licensing assistant, the responsible project manager, the NRR technical review management staff, the OGC, the NRR Project Director and Reactor Projects Division Director, the Associate Director for Projects, and the Director, NRR. These concurrences provide various check points for the quality and consistency of the staff's evaluation of exemptions. Since exemption packages are funneled through the same work group in OGC, the NRR staff has found OGC's review and concurrence to be an extremely valuable check on the adequacy and consistency of exemption packages. The practices of using prior precedents and relying on the concurrence process have worked well to ensure the quality and consistency of exemption packages.

Adequacy of 10 CFR 50.12

Exemptions issued by NRR during the past 10 years and a representative sample from the recent past were examined for specific problems and issues related to the adequacy of 50.12. The project managers that prepared the exemptions in the sample were interviewed to gain an independent assessment of the adequacy of 50.12, any proposals for improvements to 50.12, or for improvements to the overall exemption approval process. Separately, NRR Project Directors and licensing assistants were interviewed in a similar manner to gain their perspective from an oversight responsibility. Finally, OGC hearing counsel management was interviewed for insights on the adequacy of both the NRR staff's ability to document the findings appropriate to the justifying elements and the adequacy of the elements to cover all appropriate circumstances. NRR technical staff was not interviewed.

The examinations and interviews resulted in the determination that the justifying elements of 10 CFR 50.12 are adequate, appropriate, and sufficient. Therefore, the staff recommends no changes to the special circumstance provisions currently contained in 50.12. Further, the current process for approving exemptions is adequate and acceptable.

PROCESS FOR REVIEW OF EXEMPTION REQUESTS FROM PART 50 LICENSEES

The review process starts when, for whatever reason, a Part 50 licensee determines that it cannot meet a specific regulation in 10 CFR and will seek an exemption. To request an exemption, the licensee must submit an application under oath or affirmation. Although there is no written guidance that discusses what an application for an exemption should contain, such applications generally identify the specific regulation(s) from which the licensee is seeking an exemption, provide the reasons why no additional actions are necessary or specify compensatory actions that will be implemented, and give a justification for the request which would persuade the staff to conclude that the exemption was appropriate. Typically, a licensee elaborates on how the circumstances surrounding its request for exemption would satisfy the justifying elements in the governing part of the regulations (i.e., 10 CFR 50.12 for Part 50, 70.14 for Part 70, etc.). The NRR project manager assigned to the particular facility is responsible for coordinating the technical review with the appropriate technical staff and for preparing the final exemption package that will either grant or deny the exemption. As part of this review, the NRR staff researches prior precedents and coordinate with appropriate technical staff to obtain a safety evaluation.

An exemption database is available to provide historical information to the staff. The availability of this information provides an opportunity for staff to identify any prior, similar requests and identify any uniqueness in the current request. This historical information is a tool that can be used to ensure consistency in the review and approval of exemptions and to provide early identification of candidate rulemakings. To ensure the consistency of the review process and application of the justifying elements of the governing regulation, a typical exemption request is concurred in by the following people: the NRR licensing assistant, the responsible project manager, the NRR technical review management staff, the OGC, the NRR Project Director and Reactor Projects Division Director, the Associate Director for Projects, and the Director, NRR. These concurrences provide various check points for the quality and consistency of staff's evaluation of the exemption.

During the safety evaluation, the licensee's justification is examined by the NRC staff and a determination is made as to whether the request meets the justifying elements of the governing regulation and "will not present an undue risk to the public health and safety." An evaluation of probabilistic risk assessment insights, when available, may also be performed. Should the staff decide that the exemption is warranted, a memorandum to the Executive Director for Operations (EDO) from the Director, NRR is prepared with an attachment providing specific information related to the exemption. This information covers several issues: requirements of the regulation; safety significance of the exemption for the particular facility; applicability to other facilities; and whether a change to the rule for which the exemption is requested is covered in the agency's semiannual Rulemaking Activity Plan or, if not, why not. The EDO then discusses the planned action with the Chairman. Following this coordination, the exemption may be approved.

Attachment

Once approved, the issuance of an exemption is noticed in the *Federal Register*. The notice includes the exemption and the supporting safety evaluation, and is approved by the Director, NRR, with the effective date being the day that the exemption is published in the *Federal Register*. The approved exemption is documented in the docket file.



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

November 18, 1996

MEMORANDUM TO: David L. Morrison, Director
Office of Nuclear Regulatory Research

FROM: Carl J. Paperiello, Director
Office of Nuclear Material Safety and Safeguards *Carl J. Paperiello*

SUBJECT: INFORMATION ON FOLLOW-UP COMMISSION PAPER ON EXEMPTIONS

I am responding to your memorandum dated September 18, 1996. The Office of Nuclear Material Safety and Safeguards has prepared the attached information to be included in the follow-up Commission Paper on exemptions as specifically requested in your October 8, 1996 memorandum. On November 8, 1996, a preliminary electronic copy of NMSS' input was provided to Prasad Kadambi, of your staff, and a final copy was electronically provided November 14, 1996.

Attachment: As stated

CONTACT: Patricia A. Santiago, NMSS
(301) 415-7269

RES QUESTION: Provide a description of "other parts with exemption provisions."

NMSS INPUT:

OTHER PARTS WITH EXEMPTION PROVISIONS

All CFR Parts applicable to the Office of Nuclear Material Safety and Safeguards (NMSS) licensees contain or reference a general exemption clause entitled, "Specific Exemptions," which normally states, "The Commission may, upon application by any interested person, or upon its own initiative, grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest." These general criteria are used by the NMSS staff in considering licensee or certificate holder requests for exemptions in concert with the policies and procedures established by NMSS. Although this provision contains very broad and generic criteria, it enables the staff and a licensee or certificate holder to apply it to various types and categories of material operations which include fuel cycle, irradiator, laboratory, academic, medical diagnostic or therapy and many other types of applications for license or certificate holders. Historically, NMSS instituted a Policy and Guidance Directive (P&GD) in 1984 to ensure consistency in review and approval of licensee exemption requests. The P&GD contains guidance on evaluating exemption requests from licensees, and it is periodically updated to conform to revisions to regulations to ensure consistency in criteria used for specific license applications and review of exemption requests. The P&GD is currently under revision to include all specific criteria used by the staff in evaluating exemption requests. The general information needed by the NRC staff, as outlined in the current policy directs the staff to document: a description of the licensee's or certificate holder's request for exemption, circumstances surrounding the specific exemption request and why it is needed, alternatives that have been considered, and a description of how the request provides an equivalent level of safety which may include a description of compensatory measures the licensee or certificate holder would follow. This information is necessary to assure that the health and safety intent of the requirement will not be compromised and to document the staff conclusion that the request is in the interest of public health and safety and will not endanger life, or the common defense and security.

RES QUESTION: Describe recommended changes to the current processes for each program office. (Evaluate the internal process with respect to the evaluation of exemption requests and identify changes where appropriate.)

NMSS INPUT:

RECOMMENDED CHANGES TO CURRENT PROCESSES

Over the last several months, the staff reviewed approximately 200 exemption requests which had been granted over at least a 5-year period or longer. The exemptions are identified from computer databases, primarily the License

ATTACHMENT

Tracking System. The total number of exemptions is small in comparison to the 6000 or more licenses issued and numerous sections within the regulations for which a licensee could potentially seek relief. The exemption requests primarily involve medical, radiography, and irradiator applications. Most of the requests were granted pursuant to the specific exemption clause cited above. The enclosure provides more detail and summarizes the staff processes for review and approval of exemption requests from licensees.

As a result of the review of licensee exemptions approved, the staff determined that common criteria were considered in evaluating each request as outlined in the Policy and Guidance Directive. However, the staff recommended that the guidance should be revised to more clearly state each criterion used to evaluate the exemption, and a policy and procedures letter should be developed to describe the common processes used within each NMSS Division. The NMSS policy and guidance directive is currently undergoing revision to:

- 1) update guidance on granting exemptions where a new rulemaking has changed the requirement and no future licensee exemption request would be necessary,
- 2) include common criteria for both temporary and generic exemptions,
- 3) include guidance which ensures rulemaking is considered and initiated as necessary; and 4) provide guidance as to which requests need coordination with NMSS.

The intent is to ensure that the exemption approval receives an appropriate management-level review and that rulemaking actions, minimizing the need for exemptions, are identified and prioritized in a logical manner. Additional improvements identified in the following paragraphs were also instituted in the exemption review process to meet this goal.

Additional improvements identified during the NMSS review of the exemption policies and processes include establishment of a Generic Assessment Panel to provide an upper level management review, use of the License Tracking System as the primary database to identify exemptions for materials licensees, and a hierarchical approach as an additional element for raising the visibility of classes of exemptions to higher management levels (See response to last question). These improvements will provide the proper oversight and appropriate flexibility to NMSS' exemption activities and will enhance the overall process. It is also recognized that a regulation may not cover 100 percent of all types of applications within a specific category of license operations, particularly those applications involving new or evolving technologies. Licensees or applicants will need to continue to submit exemption requests based on their determination that alternatives considered for compliance were not achievable, that the intent of the requirement for which the exemption is requested is not compromised, and that the proposed exemption is in the public interest and will not endanger life or property or the common defense and security.

RES QUESTION: Determine the need for other parts of the regulations to include specific attributes or elements. Develop your preliminary recommendations for criteria for granting exemptions for materials licensees.

NMSS INPUT:

In comparing the existing exemption opportunities stated in 10 CFR 50.12 one should note the difference in operations between reactor licensees and materials licensees. Unlike materials licensees, reactor licensees are more uniform in operations and design. Licensees under Part 50 have rigorous technical specifications, operating procedures, requiring specific safety oversight by the licensee and the NRC. In considering the numerous materials licensees, it is evident that materials operations are highly varied in both the category (fuel cycle, medical therapy, irradiator, etc), operations within each category (fuel cycle, brachytherapy, teletherapy), technical ability and applications. The variability in material licensees creates difficulty in establishing criteria applicable to all and a more generic approach is needed. There are instances, however, where the criteria contained in 10 CFR 50.12 may be applied, such as exemptions involving spent fuel storage. Previous exemptions involving storage of spent fuel often used 10 CFR 50.12 criteria. Exemptions for the materials licensee areas are a tool used specifically in the regulatory process to recognize the safety requirements to be followed by a new or an atypical application.

The staff does not expect that a rule will cover each and every specific operational process, but attempts to require common safety procedures. Exceptions may be necessary based on a modified application, such as those developed with evolving technologies (e.g., high dose rate remote afterloading brachytherapy). The current exemption clause allows the interest of the public be maintained while simultaneously allowing the staff and the public a review process by which protection of the public and environment are ensured without undue burden.

To determine whether all parts of the regulations need to include specific attributes or elements similar to 50.12, the staff reviewed office policies, guidance provided to licensees, and the criteria codified in 10 CFR 50.12 for applicability to all the types of materials licensees. Based on this review, it is clear that most licensees do comply with the requirements and for the few licensees that request exemptions, the policies established and processes used demonstrate that exemption requests are practical and maintain an adequate level of safety since the staff must follow specific procedures to review, evaluate, and approve each request based on its own merit. The exemption requests approved normally result in eventual regulatory changes. The policy and procedures ensure that the requirement is evaluated consistently and logically to determine the need for rulemaking while simultaneously effectively using staff resources and reducing regulatory burdens. This is particularly noteworthy at this time considering national trends in reduction of regulatory burdens, Federal downsizing initiatives, and the agency's trend toward performance based requirements.

In summary, while there may be some merit in codifying changes similar to 10 CFR 50.12 criteria, the NMSS staff does not recommend codification nor believes it would improve the current process or provide a substantial benefit to the public. The NMSS staff bases its recommendation on: 1) the infrastructure, policies, and procedures in existence for over 10-years have ensured consistent review using specific criteria and allowed for identification of necessary rule changes; 2) recent assessments and improvements in procedures and guidance regarding evaluation of licensee exemption requests; 3) the diversity of materials licensees requirements, their unique applications and operational characteristics in comparison to reactors which must be accommodated by the regulations; 4) the agency trend toward performance vs. prescriptive requirements; and 5) the national trend to reduce regulatory burdens and regulations in general.

RES QUESTION: Describe NMSS staff's internal review processes and training.

NMSS INPUT:

For each type of request, the licensee normally provides information or information is requested in accordance with the regulatory provisions for each part, which enables the staff to complete a determination as to whether the request should be granted or denied. The information typically required includes a description of the exemption needed and why, compensatory safety measures as necessary to provide an equivalent level of health and safety as the regulation for which the exemption is being requested, and the licensee's assurance that consideration of reasonable alternatives for complying with the requirements have been completed. Some requests for exemption are considered by the staff to be "routine." These requests normally are exemptions from requirements for which a rulemaking is in progress and the staff is authorized to grant the specific request based on specific information obtained from a licensee and guidance provided within licensing guides or policy and guidance directives. The staff training includes qualification as a license reviewer in accordance with Manual Chapter 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." In addition, the manual requires reviews of appropriate policy and guidance directives, regulatory guides, and information notices, such as those specific to granting of exemption requests.

The information requested from, and provided by, a licensee is described in the policies and procedures and includes a description of the request for exemption, circumstances surrounding the need, alternatives the licensee has considered, and a description of how the licensee's request provides an equivalent level of safety which may include a description of compensatory measures the licensee would follow. Often, a licensee provides specific information on dose rates and expected doses to demonstrate compliance with the basic radiation safety standards established in 10 CFR Part 20. The licensee must demonstrate that the intent of the requirement is not compromised for which the exemption is being requested. An NMSS technical

review of the exemption request and the circumstances and merits of the particular action must be completed for exemption requests that have not been previously approved or identified as specifically requiring such review within the policy and guidance directive.

As part of the NMSS review of the exemption requests and processes used for evaluation of each request, additional bases were considered that could be used in assigning priorities to the exemptions requiring rulemaking action, and in determining the need for upper-management visibility. As an example, to improve the process of reviewing generic issues, including exemption requests, and identifying and initiating appropriate rulemaking actions, IMNS recently established (February 1996) a Generic Assessment Panel (GAP). The majority of exemptions requests are within the IMNS program areas. The panel is chaired by the Deputy Division Director and includes appropriate staff. Among its tasks, GAP reviews exemption requests for their generic applicability and provides an additional method in providing NMSS input to the annual review of rulemaking needs and priorities, that is part of the Rulemaking Activity Plan review process. A review of the exemptions issued to licensees requesting an exemption demonstrates that most requests for exemptions have led to rulemaking initiatives.

Because the regulatory system is neither entirely performance- nor entirely specification-based, the staff considered the addition of a "significance" measure for the regulations for which exemptions are being granted. In contrast to reactor regulations, materials regulations are defined by a hierarchy inherent to the Agreement State program--the Division (proposed Component) levels assigned to each section of the regulations. The Division 1 and 2 compatibility components are the basic radiation protection standards or other regulations that must be (essentially) identical in Agreement State regulations, or regulations addressing basic principles of radiation safety and regulatory functions. Exemptions to Division 1 and 2 regulations would require Office-level management notification. Approximately 11 and 30 percent of the exemptions fall in the Division 1 and 2 categories, respectively. The other exemptions relate to Division 3 regulations or are not subject to compatibility designations. To the degree that Division 3 exemptions have a commonality (e.g., driven by changes in technology) that can be resolved through rulemaking, the rulemakings should be pursued as licensee needs determine and resources allow. It should be noted that the RES Commission Paper (SECY-96-147) considered these factors.

Following the NMSS technical review either recommending approval or denial, the Office of General Counsel reviews the request and the staff's response. The regional office is then given information upon which to grant the exemption request, request further information, or deny the request typically notifying the licensee of its option to request a hearing. Administratively, the exemption granted is identified by the CFR section and entered into the License Tracking System. This system allows the staff to generate lists of exemptions for specific licensees or requirement sections and assists in reviews of rulemaking activity plans and determinations for rulemaking needs to minimize the exemptions issued.